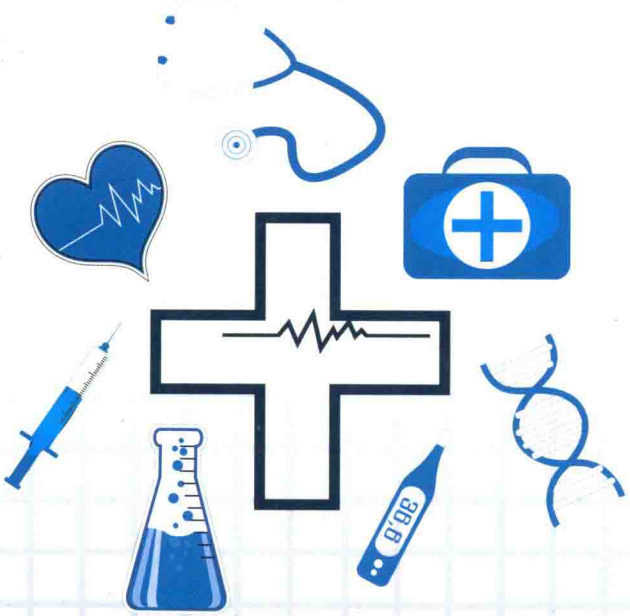
普通高等教育医药管理类专业核心课程系列教材

医疗器械专业英语

赵学旻 编著

Medical Devices English



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编委会

总 序

2012 年 8 月，国家卫生与计划生育委员会提出了“健康中国 2020”战略，这一战略是以提高人民群众健康为目标，以解决危害城乡居民健康的主要问题为重点，坚持预防为主、中西医并重、防治结合的原则，采用适宜技术，以政府为主导，动员全社会参与，切实加强对影响国民健康的重大和长远卫生问题的有效干预，确保到 2020 年实现人人享有基本医疗卫生服务的重大战略目标。“健康中国”战略思想的提出，是卫生系统探索中国特色卫生改革发展道路集体智慧的结晶，是卫生战线对中国特色卫生事业发展理论体系的丰富发展，是构建和谐社会的重要基础性工程，有利于全面改善国民健康，确保医改成果为人民共享，也有利于促进经济发展方式转变，充分体现贯彻落实科学发展观的根本要求。

为了确保“健康中国 2020”战略的贯彻落实，国家卫生与计划生育委员会在《“健康中国 2020”战略研究报告》中特别提出了八大政策措施，其中之一就是实施“人才强

卫”战略，提高卫生人力素质。我校是一所新建的市属本科医学院校，主要培养特色鲜明、实用性强、服务于临床医学和人类健康的应用型专门人才。

为响应国家卫计委“人才强卫”战略，为“健康中国”培养更多、更好的实用型人才，特组织全国部分医学院校、医院、相关政府部门和行业企业的专家、学者，共同编写了一套“普通高等教育医药管理类专业核心课程系列教材”，该套教材涵盖了医药物流管理、医药市场营销、医疗器械产品监管等相关学科领域。与同类教材相比，该套教材有如下一些特色：

第一，在教材编写的整体思路上，以培养学生分析问题、解决问题的综合应用能力为出发点，不过分追求理论的完整性和知识的系统性，凸显学生综合技术实践意识和实践能力的培养，强调学以致用。

第二，在教材内容的选择上，贯彻了“新、精、适”的原则。“新”是指每本教材内容及时反映了该学科的最新发展和最新技术成就，并将从实践中总结、提炼出来的一些新技术、新方法融入教材中去，保证教师教的都是最先进的，学生学的都是最适用的，避免了知识的陈旧落后。“精”是指精选学生终身受益的基础知识和基本技能，力求把含金量高的知识传承给学生。“适”是指教材的知识深度和难度以及知识量适合应用型本科教育层次、适合培养目标的既定方向、适合应用型本科院校学生的理解程度和接受能力。

第三，在教材的呈现形式上，采用项目驱动、问题导学的“教、学、做”一体化形式，并有机融合了“基于问题学习”的建构主义教学方式和情境教学方法，突出应用型本科人才培养的职业特性。

相信本套教材的出版问世，必将有助于促进我国普通高等院校医药管理类专业应用型本科人才培养水平的提高。

黄　纲

上海健康医学院院长　博士生导师

2015 年 8 月

前 言

医疗器械产品是与人体密切相关的特殊物品。现代医学对疾病的预防和治疗在很大程度上依赖先进医疗器械设备的诊断结果。医疗器械产业是多学科交叉、知识密集、技术密集的高技术产业。它是全球共同关注的具有高度战略地位的新兴行业，发展水平关系到人民群众身体健康和生命安全，代表了一个国家的综合实力与科技发展水平。近年来，我国医疗器械市场发展迅速，医疗器械进口保持强劲增长。大量的进口产品使用说明书、技术手册需要翻译成中文，翻译质量直接关系到医疗器械的安全性和有效性。同时，我国积极鼓励医疗器械技术创新和高端医疗器械产品研发，医疗器械行业与国外同行学术交流日益频繁，医疗器械专业英语凸显其重要性。

本教材结合英语交际法、项目式教学、建构主义等先进的外语教学理念，以项目为导向，以任务为驱动，注重培养学生的实践能力与职业素质。本教材特色鲜明，体现以下亮点：

1. 以兴趣为起点

教材针对专业内容设计富有趣味的导文，激发学生兴趣，调动情感因素。

2. 以项目为单位

根据职业方向，设计电生理诊断仪器、医学超声仪器、医学影像设备、生命支持设备、植入医疗器械、手术器械、医疗器械市场等 10 个项目，理论与实践紧密结合。

3. 以任务为框架

围绕职业，针对学习材料、学习内容设计听说读写、对话、讨论等灵活多样的任务，让学生“以语言做事”，引导教师以任务为核心组织教学，提高互动。

4. 材料难度适中，且材料安排图文并茂

材料选择强调真实性、实用性、职业性。材料改变传统专业英语深奥晦涩的面貌，降低语言难度，在真实、实用的基础上，达到专业性与趣味性的统一。

5. 强调职业能力与创新意识

将专业知识融入真实职场情景，培养职业英语交际能力和职业精神。项目融入器械发明的小故事，设计创新型任务，引导学生大胆预测器械的未来发展方向，激发学生的创新能力。

本教材在编写过程中力求审慎，但因编写时间仓促，加之水平有限，如有错误之处，恳请专业人士和广大读者提出宝贵意见。

赵学旻

2015 年 7 月

Contents

Project 1

Medical Device

Learning Objectives

After studying project 1, you should be able to:

1. grasp the definition and classification of medical device
2. determine whether or not a product is a medical device
3. determine the classification of a medical device
4. become familiar with some medical device organizations such as GHTF, and FDA.

With innovation and the rapid advancement of technologies, medical devices are currently one of the fastest growing industries. Like medicines and other health technologies, medical devices are essential for patient care–at the bedside, at the rural health clinic or at the large, specialized hospital.

Section 1 Medical Device Definition

Lead-in

1. Could you list the names of some medical device?
2. Have you heard of GHTF? What kind of an organization is GHTF?

GHTF

The Global Harmonization Task Force (GHTF) was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems.

GHTF was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The GHTF was comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework. Beginning in 2006, membership expanded to include three Liaison Body members: Asian Harmonization Working Party (AHWP), International Organization for Standardization (ISO), and International Electrotechnical Commission (IEC).

The purpose of the GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade. The primary way in which this purpose was accomplished was via the publication and dissemination of harmonized documents on basic regulatory practices. These documents, which were developed by five different GHTF Study Groups, provided a model for the regulation of medical devices that can then be adopted/implemented by national regulatory authorities.

The organization GHTF no longer exists, and has been permanently replaced by the IMDRF. The International Medical Device Regulators Forum (IMDRF) is continuing the work of GHTF.

Vocabulary Help

Global Harmonization Task Force		全球协调工作组
liaison [li'eiz(ə)n]	*n.*	联络
Asian Harmonization Working Party		亚洲协调工作组
International Organization for Standardization		国际标准化组织
International Electrotechnical Commission		国际电工委员会
convergence [kən'və:dʒəns]	*n.*	统一
dissemination [di:semi'neiʃn]	*n.*	宣传
International Medical Device Regulators Forum		国际医疗器械监管者论坛

Text

Medical Device Definition

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, X-rays machines and medical lasers.

The Global Harmonization Task Force (GHTF) proposed the following definition for medical device.

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro regent or calibrator, software, material or other similar or related article:

intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

◎ diagnosis, prevention, monitoring, treatment or alleviation of disease.

◎ diagnosis, monitoring, treatment, alleviation of or compensation for an injury.

◎ investigation, replacement, modification, or support of the anatomy or of a physiological process.

◎ supporting or sustaining life.

◎ control of conception.

◎ disinfection of medical devices.

◎ providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body.

and

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

This definition provides a clear distinction between a medical device and other products such as drugs or biological products. Medical devices differ from drugs in that they do not achieve their intended use through chemical reaction and are not metabolized in the body. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. Biological products include blood and blood products.

A clear understanding of the medical device definition helps us to determine whether or not a product is a medical device.

New Words

bedpan ['bedpæn]	*n.*	便盆
programmable [ˌprəu'græməbl]	*adj.*	可程序化的
pacemaker ['peismeikə]	*n.*	心脏起搏器
laser ['leizə]	*n.*	激光
reagent [ri:'eidʒənt]	*n.*	试剂
monoclonal [ˌmɔnə'kləunəl]	*adj.*	单克隆的，单细胞繁殖的
antibody ['ænti,bɔdi]	*n.*	抗体
radiation [ˌreidi'eiʃən]	*n.*	辐射，放射线
diagnostic [daiəg'nɔstik]	*adj.*	诊断的
ultrasound ['ʌltrəsaund]	*n.*	超声，超声波
implant [im'plɑ:nt]	*n.*	植入物
calibrator ['kælibreitə]	*n.*	校准器

alleviation [ə,li:vi'eiʃən]	*n.*	减轻，缓和
anatomy [ə'nætəmi]	*n.*	解剖
physiological [,fiziə'lɔdʒikəl]	*adj.*	生理的，生理学的
conception [kən'sepʃən]	*n.*	妊娠，怀孕
specimen ['spesimən]	*n.*	样本
pharmacological [,fɑ:məkə'lɔdʒikəl]	*adj.*	药物学的，药理学的
immunological [,imjunə'lɔdʒikəl]	*adj.*	免疫学的
metabolic [,metə'bɔlik]	*adj.*	新陈代谢的
metabolize [mi'tæbəlaiz,]	*v.*	使新陈代谢

Professional phrases

1. tongue depressor 压舌器
2. micro-chip technology 芯片技术
3. surgical device 外科手术装置
4. test kit 试剂盒
5. monoclonal antibody technology 单克隆抗体技术
6. in vitro 体外

Key Notes to the Text

1. "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro regent or calibrator, software, material or other similar or related article:

intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

◎ diagnosis, prevention, monitoring, treatment or alleviation of disease.

◎ diagnosis, monitoring, treatment, alleviation of or compensation for an injury.

◎ investigation, replacement, modification, or support of the anatomy or of a physiological process.

◎ supporting or sustaining life.

◎ control of conception.

◎ disinfection of medical devices.

◎ providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

本句可译为："医疗器械"包括仪器、设备、器具、机械、器械、植入物、体外试剂或校准器、软件、材料或其他类似物或相关的物品，生产厂商预期单独或者组合供人类使用以达到以下一种或多种特殊目的：

◎对疾病的诊断、预防、监护、治疗或缓解；

◎对损伤的诊断、监护、治疗、缓解或补偿；

◎对解剖或生理学过程的研究、替代、调节或支持；

◎对生命的支持和维持；

◎对妊娠的控制；

◎对医疗器械的消毒；

◎通过对来自人体样本的体外检测，提供用于诊断和治疗目的的信息；

并且其对于人体体表及体内的主要预期作用不是通过药理学、免疫学或代谢的手段获得，但可能利用这些手段辅助达到其预期作用。

2. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device.

某些应用于医学及声称具有医学效用的电子辐射发射产品也符合医疗器械的定义范围。

Practical skills

I. In pairs or small groups, discuss the questions.

1. What is medical device?
2. Go to the website www.imdrf.org, and review the GHTF document providing the medical device definition.
3. Visit the website www.fda.gov, and search for the medical device definition regulated by FDA.
4. What is the major distinction between a medical device and drug?

II. Choose the right answer.

1. What kind of an organization is GHTF?

A. It is an organization responsible for the regulation of medical device in USA

B. It is engaged in the scientific research of medical device

C. Its purpose is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices

D. It is an official organization of representatives from national medical device regulatory authorities and the regulated industry

2. Which of the following statement is not true about GHTF?

A. It includes three Liaison Body members: The International Medical Device Regulators Forum (IMDRF), International Organization for Standardization (ISO), and International Electrotechnical Commission (IEC)

B. It works on the publication and dissemination of harmonized documents on basic regulatory practices to provide a model that can then be adopted/implemented by national regulatory authorities

C. It has been permanently replaced by the International Medical Device Regulators Forum (IMDRF)

D. It was established by 5 five founding members in 1992

3. Medical devices differ from _____ in that they do not achieve their intended use through chemical reaction and are not metabolized in the body.

A. biological products B. drugs

C. blood products D. electronic radiation emitting products

4. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a _____.

A. medical device B. biological product

C. chemical product D. drug

5. Blood and blood products are _____.

A. biological product B. medical device

C. chemical product D. pharmaceutic product

6. Which of the following statement is true about medical device?

A. Medical device is used for human beings and animals